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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,235	08/23/2001	Frank Himmelsbach	5/1256	1687
28505	7590	06/18/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,235

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a -CH=CH-CH=CH, -CH=CH-NH, or -CH=N-NH group;
B is group (a);
or **A together with B** represent a group selecting from groups (a)-(g);
D is group (a);
or **C together with D** represent a group selecting from groups (a)-(g);

classified in classes 514, and 544, various subclasses depending on substituents.

Group 2: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a -CH=CH-CH=CH, -CH=CH-NH, or -CH=N-NH group;
B is group (b) or (c);
D is group (a);
or **C together with D** represent a group selecting from groups (a)-(g);

classified in classes 514 and 544, various subclasses depending on substituents.

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Group 3: Claims 1-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$, or $-\text{CH}=\text{N}-\text{NH}$ group;
B is a group selecting from groups (d)-(g);
D is group (a);
or **C together with D** represent a group selecting from groups (a)-(g);

classified in classes 514 and 544, various subclasses depending on substituents.

Group 4: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$, or $-\text{CH}=\text{N}-\text{NH}$ group;
B is a group selecting from groups (h), (i), (n) or (o);
or **A and B** together represent group (h);
D is group (a);
or **C together with D** represent a group selecting from groups (a)-(g);

classified in classes 514 and 544, various subclasses depending on substituents.

Group 5: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$, or $-\text{CH}=\text{N}-\text{NH}$ group;
B is a group selecting from groups (j) – (m);

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D is group (a);
or **C together with D** represent a group selecting from groups (a)-(g);

classified in classes 514 and 544, various subclasses depending on substituents.

Group 6: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a -CH=CH-CH=CH, -CH=CH-NH, or -CH=N-NH group;
B is group (a);
or **A together with B** represent a group selecting from groups (a)-(g);
D is group (b) or (c);

classified in classes 514, and 544, various subclasses depending on substituents.

Group 7: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

X is a nitrogen atom;
R₁ and R₂ together do not represent a -CH=CH-CH=CH, -CH=CH-NH, or -CH=N-NH group;
B is group (a);
or **A together with B** represent a group selecting from groups (a)-(g);
D is a group selecting from groups (d) – (g);

classified in classes 514, and 544, various subclasses depending on substituents.

Group 8: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with the following substituents:

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X is a nitrogen atom;
R₁ and R₂ together do not represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$,
or $-\text{CH}=\text{N}-\text{NH}$ group;
B is group (a);
or **A together with B** represent a group selecting from groups (a)-(g);
D is a group selecting from groups (h), (i), (n), and (o);
or **C and D** together represent group (h);

classified in classes 514, and 544, various subclasses depending on substituents.

Group 9: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e.,
compounds, composition, and method of treatment) of formula (I) with the
following substituents:

X is a nitrogen atom;
R₁ and R₂ together represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$, or $-\text{CH}=\text{N}-\text{NH}$ group;
B is group (a);
or **A together with B** represent a group selecting from groups (a)-(g);
D is a group selecting from groups (j) - (m);

classified in classes 514, and 544, various subclasses depending on substituents.

Group 10: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e.,
compounds, composition, and method of treatment) of formula (I) with

X is a nitrogen atom;
R₁ and R₂ together represent a $-\text{CH}=\text{CH}-\text{CH}=\text{CH}$, $-\text{CH}=\text{CH}-\text{NH}$, $-\text{CH}=\text{N}-\text{NH}$;

classified in classes 514, and 544, various subclasses depending on substituents.

Further restriction will be required if this group is elected.

Group 11: Claims 1-7, and 9-13 (part of each), drawn to the **remaining** subject
matter (i.e., the subject matter **not** in groups 1-10) of formula (I) with **X** is a

nitrogen atom; classified in classes 514, and 544, various subclasses depending on substituents. Further restriction will be required if this group is elected.

Group 12: Claims 1-7, and 9-13 (part of each), drawn to the subject matter (i.e., compounds, composition, and method of treatment) of formula (I) with

X is a methine group substituted by a cyano group;

classified in classes 514, and 546, various subclasses depending on substituents.

Further restriction will be required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

A. Although the invention of Groups 1 – 11 share a core of *amino-quinazoline*, such a core alone does not sufficiently define the invention, nor it is applicant's contribution to the art. Therefore, the compound of formula I is defined by the *combination* of the amino-quinazoline with variables A-D, R₁ and R₂. It is this combination that gives the compound in each group its unique physical, and chemical properties as well as biological activity. Thus, a reference that anticipated one group would not do so to the others. Consequently, a separate search is needed for each group, which in turn, poses a burden of searching.

B. The invention of group 12 is drawn to compounds of an entirely different core (i.e., *amino-quinoline*). Again, a reference that anticipated this group would not do so to groups 1-11. Therefore, a separate search is necessary, which raises a burden of searching.

Therefore, inventions of Group 1 – 12 are unrelated since they are not disclosed as capable of use together, and they have different physical, chemical as well as biological effects (MPEP § 806.04, MPEP § 808.01).

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Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Groups 2-12 (and vice versa), and the search for 12 different inventions would indeed impose a serious burden upon the examiner in charge of this invention, restriction for examination purposes as indicated is proper.

Due to the complexity of the grouping, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

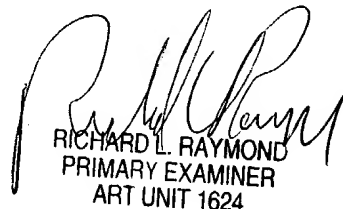
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

June 14, 2004



RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624